DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 30, 2015

Vitalograph Ireland Ltd.
Tom J. Healy
Regulatory Affairs/QA Manager
Gort Road Business Park
Ennis, Co Clare
Ireland

Re: K142642
Trade/Device Name: Vitalograph Model 6600 Compact
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: May 25, 2015
Received: May 27, 2015

Dear Mr. Healy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142642

Device Name
Vitalograph Model 6600 Compact

Indications for Use *(Describe)*
The Vitalograph Model 6600 COMPACT is intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on adults and paediatrics, 5 years and older. The device is intended to be used as a spirometer which measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC or connected to compatible Vitalograph or third party devices to acquire, view, store and print the device output.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510K Summary

as required by 21 CFR 807.92

1. Company Information:
   Name: Vitalograph (Ireland) Ltd
   Address: Gort Road Business Park, Ennis, Co Clare, Ireland.

   Tel: +353656864100
   Fax: +353656829289.

2. Contact Person / Official Correspondent:
   Mr. Tom J Healy
   Regulatory Affairs / Quality Assurance Manager

3. Date prepared:
   29th June 2015.

4. Device Trade Name:
   Vitalograph Model 6600 Compact

5. Common / Usual name:
   Diagnostic Spirometer,
   Vitalograph Compact Expert

6. Classification number:

   Class 2 Diagnostic Spirometer as classified per 21 CFR 868.1840.
   Product Code BZG.

7. Predicate Device:

Manufacturer	: Vitalograph
Device Name	: Model 7000 Spirotrac
510(k) No	: K141546, Class 2, Product Code BZG.
Manufacturer	: Vitalograph
Device Name	: Model 2120
510(k) No	: K100687, Class 2, Product Code BZG.

8. Description of Device:

Vitalograph Model 6600 Compact, running Vitalograph Model 7000 Spirotrac software, ref 510(k) K141546, shall provide a mains-powered desktop spirometer for creating, adding and recalling subjects and performing Spirometry testing on those subjects to aid in the measuring the effect of lung disease on pulmonary function.

Model 6600 Compact will also, via the Spirotrac software, connect to compatible third party devices to read and display the output from these devices to allow the

information to be retained with the subject. All connected compatible third party devices are those cleared via Model 7000 510(k) K141546.

Compatible third party devices are:

- Nonin iPod
- A&D Blood Pressure
- Corscience BT12
- A&D weighing scales

The intended use of the Compact is in the simple assessment of respiratory function through the measurement of dynamic lung volumes i.e. spirometry.

Its primary functions are:

1. Interaction will be via the touch Screen interface.
2. Running the Spirotrac software, as cleared in K141546, The model 6600 Compact performs spirometric measurements using the established fleisch Pneumotachograph, using single breath and multiple-breath testing techniques, to display and record lung volumes and flow rates (including FVC, FEV1, FEV6, PEF, MVV and VC) and their sub-divisions to aid in the measuring the effect of lung disease on pulmonary function
3. Record subject demographic data.
4. Produce printed reports to external printers.

9. Indications for Use:

The Vitalograph Model 6600 COMPACT is intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on adults and paediatrics, 5 years and older. The device is intended to be used as a spirometer which measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC or connected to compatible Vitalograph or third party devices to acquire, view, store and print the device output.

10. Technological Characteristics

The differences between the Model 6600 Compact and the predicate devices are the software which is being used as the primary interface with the user. This software was previously cleared, ref K141546. The profile and weight of the Model 6600 Compact also differs where the Model 6600 is larger.

These differences do not pose any risks to the intended use of the device. The Model 7000 Spirotrac software (K141546) to be used independently of a PC within a controlled environment with all of the functions of a PC still available.

For performance, the same flow measurement and operating principles are used on the predicate devices as are on the Vitalograph Model 6600 Compact device. The flow circuit will use the same exact circuit and transducer as used in the Vitalograph Model 2120 {ref K100687}. While, a new industrial design has been created, this has the

same touchscreen input mechanism, interface and functionality as was cleared for the Model 7000 Spirotrac, {ref K141546}.

The indications for use for the Vitalograph Pneumotrac now include pediatric population in line with the updated FDA guidance. The Model 6600 has the same indications for use, including pediatric population, as the Model 7000 as cleared under K141546. No new testing was required for this revised indication for use. No new risks have been introduced as a result of pediatric population inclusion. The device complies with the existing international performance standards to cater for all population groups.

Materials used continue to be those materials that have been previously used and do not introduce any new risks in relation to safety and effectiveness.

In relation to Patient interface accessories the Model 6600 will use the established Model 2820 and Model 2020 mouthpieces which have their own previous clearances and active device listings. See comparison table below.

The characteristics of the Model 6600 Compact are similar to those of the predicate devices listed in comparison table below. The similarities are

- Identical user interface, and software, as cleared via model 7000 Spirotrac, ref 510(k) K141546.
- Same indications for use (Clarification of pediatric population and parameters measured)
- Some operating principle and flow measurement principles.
- Same parameters calculation.
- Same method of use
- Same performance when bench tested against performance standards.
- Same patient interface accessories

Risks have been evaluated and the performance has been validated. This validation is on file for all devices.

	Compact Model 6600	**K141546 Spirotrac Model 7000 {predicate}**	**K100687 Model 2120 {predicate}**
Spirometry - acquire, view, store and print measures and waveforms of pulmonary function	Yes	Yes	Yes
ECG waveforms - view, store, print	Yes	Yes	No
ECG waveforms - acquire	Yes, From compatible device.	Yes, From compatible device.	No

ECG waveform-view, store, print	Yes	Yes	No
ECG Interpretation via algorithms	Yes	Yes	No
Ambulatory Blood Pressure - retrieve, view, store and print patient ambulatory blood pressure history	Yes, from compatible device.	Yes, from compatible device.	No
Spot Oximetry download, view.	Yes, From compatible device.	Yes, From compatible device.	No
Weight (measurement)	Manual entry or download via connection to compatible device	Manual entry or download via connection to compatible device	No
Microsoft windows Operating Systems Supported:	Yes	Yes	No
Database:	MS SQL Server	MS SQL Server	MS SQL when downloaded to Spirotrac {K100687 & K141546}
Where used	Hospital, Health centre, primary care practices and clinics	Hospital, Health centre, primary care practices and clinics	Hospital wards, health centres and homes
Networked operation	Yes	Yes	No
Subject Management: Demographic Entry, Maintenance and Deletion	Yes	Yes	Yes
Report Printing	Yes	Yes	Yes
Spirometry testing	Yes	Yes	Yes
Trending Graphs for Spirometry Results	Yes	Yes	Yes, when downloaded to Spirotrac {K100687 & K141546}
Spirometry Predicted Value Equations	Yes	Yes	Yes

Population Group Management	Yes	Yes	Yes
Data Import/Export	Yes	Yes	Yes
Subject and Spirometry Data Export	Yes	Yes	Yes
Manual data entry of results	Yes	Yes	Yes
Data export via Email	Yes	Yes	Yes, when downloaded to Spirotrac {K100687 & K141546}
Database Management	Yes	Yes	Yes, when downloaded to Spirotrac {K100687 & K141546}
Colour Display	Yes	Yes	No
Target Population	Adult & Paediatric	Adult & Paediatric	Adult, Paediatric
Communication	Bluetooth, USB,	Bluetooth, USB,	USB, Micro SD card
Storage	Dependent on storage media	Dependent on storage media	Non-volatile data storage
Sterile	No	No	No
Regulatory (USA):	FDA - 510(k) Class 2	FDA - 510(k) Class 2. K141546	FDA - 510(k) Class 2 K100687
Performance standards	ATS/ERS 2005 ISO 26782, ISO 23747,	ATS/ERS 2005 ISO 26782, ISO 23747,	ATS/ERS 2005 ISO 26782, ISO 23747,
Safety Standards IEC / EN 60601 {EN 60601-1-1 and EN 60601-1-2}	Yes	Yes, for connected compatible devices	Yes
Performance Standards {incl bench tests}:	ATS ERS 2005, ISO 23747:2009 for PEF {formerly EN13826:2003}. EN ISO 26782:2009 Drop test. Vibration testing Bump Tests. Storage conditions.	ATS ERS 2005, ISO 23747:2009 for PEF {formerly EN13826:2003}. EN ISO 26782:2009	ATS ERS 2005, ISO 23747:2009 for PEF {formerly EN13826:2003}. EN ISO 26782:2009 Drop test. Storage conditions.

	Operating temperature		Operating temperature
Device materials	ABS plastic Body, Silicone Rubber, Stainless Steel, Aluminium, TPX plastic	N/A. Software	ABS plastic Body, Silicone Rubber, Stainless Steel, Aluminium, TPX plastic
Device weight	2.5KG	N/A. Software	0.230Kg
Dimensions	375*235*110mm	N/A. Software	160x100x45mm
Patient interface accessories	Model 2820 BVF Mouthpiece, Singe; patient use. 510(k) K942779. Product Code BZG	Dependent on connecting compatible third party device.	Model 2820 BVF Mouthpiece, Singe; patient use. 510(k) K942779. Product Code BZG Model 2020 SafeTway Mouthpiece. Singe; patient use {Class 1, 510(k) exempt, with an active device listing. Device listing: D141382. Product Code BYP, Vitalograph Nose Clip, Singe; patient use {Class 1, 510(k) exempt, with an active device listing. Device listing D130170. Product Code BXJ
Product Code, Class, CFR	BZG, Class 2, 868.1840	BZG, Class 2, 868.1840	BZG, Class 2, 868.1840
Indications for Use	The Vitalograph Model 6600 COMPACT is intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on adults and paediatrics, 5 years and older. The device is intended to be used as a	The Vitalograph Model 7000 Spirotrac is intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on both adult and pediatric patients. The device is a PC based software	The device is a battery operated spirometer which measures three basic patient respiratory parameters {FVC, MVV and VC}. The model 2120 is a hand held spirometer designed for lung function testing in a variety of

	spirometer which measures patient respiratory parameters including FVC, FEV1, FEV6, PEF, MVV and VC or connected to compatible Vitalograph or third party devices to acquire, view, store and print the device output.	application which is intended to be used as a spirometer or connect to compatible Vitalograph or third party devices to acquire, view, store and print the device output.	environments such as hospital wards, health centres and private homes. The model 2120 can be configured as a stand-alone spirometer or connected to a printer.

The Vitalograph Model 6600 underwent validation testing to ensure performance according to its specifications against current standards. These tests included performance testing against international standards such as

- ISO 26782{Anaesthetic and respiratory equipment -- Spirometers intended for the measurement of time forced expired volumes in humans},
- ATS/ERS 2005 {ATS/ERS Task Force: Standardisation of Lung Function Testing} and
- ISO 23747 {Anaesthetic and respiratory equipment -- Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans}.

Mechanical shock testing was also performed to evaluate the effects on the device during transport.

These tests included:

- Drop test of the packaged device from a specified height onto all corners and edges.
- Random Vibration, sinusoidal Vibration, and Bump Tests.
- Storage conditions testing.
- Operating temperature limits testing.

All tests and validations demonstrated satisfactory results.

As with the predicate device the Model 6600 Compact successfully passed the performance requirements of these tests. Evidence of successful completion of tests and validations has been provided with this submission.

11. Conclusion:

The characteristics of the Model 6600 Compact are similar to those of the predicate devices listed.

Based on the above, including the successful completion of all device testing Vitalograph conclude that this device is as safe and as effective as the predicate devices.
No new issues of safety or effectiveness have been introduced as a result.